bi-pro marketing limited

370 Speedvale Avenue W.
Guelph, ON · Canada · N1H 7M7
toll free: 1-800-263-7430
phone: +1 (519) 824-2381
fax: +1 (519) 824-9472
web: www.bi-pro.com
e-mail: marketing@bi-pro.com

Food and Drug Administration

Docket Number: 2002N-0278

Webpage: www.fda.gov/OHRMS/DOCKETS/98fr/04-8517.htm

Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Comments

1) **FDA Outreach Programs** – When the BTA was initially launched, FDA committed to conducting outreach programs to train stakeholders such as submitters, transmitters and brokers. It is unclear to what extent such an outreach program was implemented. It certainly never made it to Canadian exporters who submit Prior Notice information through the PNSI system. An expanded outreach program that would educate and train all stakeholders should be considered in order to reduce errors and ensure accurate information is being entered into the system.

2) **PNSI Database** – the PNSI system should allow users to build a database of standard entry information such as names and addresses of producers, H.S. tariff numbers, FDA codes, etc. The technology exists to allow this on a large basis and is already utilized on secure systems such as courier company websites. This would shorten the amount of time required to enter information into PNSI.

3) **Time Frames** – FDA time frames for submitting Prior Notice should be shortened to be the same as CBP's Advanced Electronic Information time frames. This will present a more streamlined flow of information and avoid unnecessary duplication. For exporters close to the Canada/US border, a shortened time frame will prevent supply chain slow downs caused by truckers having to wait until current FDA Prior Notice time frames have elapsed.

4) **Required Information Volumes** – the current FDA requirement of a separate prior notice for each product sku, presents an overwhelming volume of work for exporters. This can be resolved by providing space to register a listing of all products, sizes, colors, etc. on each shipment. This method would still give FDA advanced visibility on items being imported but would lighten the administrative workload necessary with the current system.

5) **Penalties** - penalties associated with "untimely Prior Notice" should not be considered as a "Category 3" violation. The refusal and fine provision for a shipment showing up at the border in advance of the 2-hour time frame elapsing seems excessive for the type of infraction. Consideration should be given to lowering the penalty for this type of offense.

6) **Protection of Proprietary Information** – the current regulations require the submission of information to the FDA by the exporter which, under the normal course of business, would not be available to the exporter. Re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. To do so will allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller.

We recommend that the PNSI contain a space that would allow entry of just the manufacturer's FDA registration number without the requirement for the name and address of the manufacturer. The FDA database should be able to identify the manufacturer by their registration number, thereby giving the required visibility to FDA while maintaining proprietary confidentiality within the business environment. Re-sellers would be more accepting of providing FDA numbers if they knew the identification of their suppliers would still be confidential.